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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bobroff et al.	Art Unit:	3761
Serial No.:	10/798,060	Examiner:	Melanie J. Hand
Filed:	March 10, 2004	Customer No.:	41883
Title:	Postoperative Fluid Monitoring And Alert System		

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APPEAL BRIEF (AMENDED)

This Amended Appeal Brief is being filed in response to the Notification of Non-Compliant Appeal Brief mailed February 13, 2009. That notification indicated that the original Appeal Brief filed on January 12, 2009, was defective for failing to provide a concise explanation of the subject matter in Claim 15 (Section V of the Brief). Though the original brief stated that claim 15, similar to claim 1, found support in all the same locations as claim 1, applicants have now expanded the explanation of claim 15 to list page and line numbers in the specification where support can be found for claim 15.

Please charge any fees required for this Amended Appeal Brief filing to Deposit Account No. 50-3067.

(i) Real Party In Interest

The real party in interest is Haemonetics Corporation. Haemonetics is the assignee of the present application by the assignment from the inventors recorded at the USPTO on December 22, 2006 at Reel # 018685 and Frame # 0242.

(ii) Related Appeals and Interferences

None.

(iii) Status of Claims

Claims 1 - 15 are pending in the application.

Claim 13 is withdrawn.

Claims 1 -12, 14 and 15 are rejected and are the subject of this appeal.

(iv) Status of Amendments

No amendment has been filed subsequent to the final rejection of the claims in the action dated January 8, 2008.

(v) Summary of Claimed Subject Matter

Claims 1 and 15 are independent.

Claim 1 defines a postoperative fluid monitoring and alert system and is described generally in the specification at page 3, line 6 through line 17 and in Figures 1 and 2. The claim defines the fluid monitoring and alert system 10 as comprising a fluid collection device 12 (page 9, lines 10-29) having a vacuum reservoir 50 (page 11, lines 1-16) configured to be placed in communication with a suction pathway that is at least partially defined by a surgical drain tube 18 (page 9, lines 10-29). Claim 1 further defines at least one liquid collection sensor configured to obtain data from the suction pathway, such as a camera as described at page 12, line 15 through page 13 line 8 and in FIGS. 3 and 4.

Claim 1 further defines a controller 24 (page 10, lines 18-28) connected to the

liquid collection sensor (page 12, lines 16-18) and that is configured to receive current procedure data from the sensor, save the data to create historical procedure data, compare the current procedure data to the historical procedure data as described at various points in the specification:

page 3, lines 1-6;

page 3, line 26 – page 4, line 7;

page 5, line 10-17;

page 6, line 9-23;

page 16, line13 - page17, line 4;

page 19, line 23 – page 20, line 20;

Claim 1 also recites that an alarm is activated when predefined trends in the data are detected (page 20, lines 25-27).

Claim 15 defines a postoperative fluid monitoring and alert system and is described generally in the specification at page 3, line 6 through line 17 and in Figures 1 and 2. The claim defines the fluid monitoring and alert system 10 as comprising a fluid collection device 12 (page 9, lines 10-29) having a vacuum reservoir 50 (page 11, lines 1-16) configured to be placed in communication with a suction pathway that is at least partially defined by a surgical drain tube 18 (page 9, lines 10-29). Claim 15 further defines at least one liquid collection sensor configured to obtain data from the suction pathway, such as a camera as described at page 12, line 15 through page 13 line 8 and in FIGS. 3 and 4.

Claim 15 further defines a controller 24 (page 10, lines 18-28) connected to the liquid collection sensor (page 12, lines 16-18) and having instructions to receive current procedure data from the sensor, save the data to create historical procedure data, compare the current procedure data to the historical procedure data as described at various points in the specification:

page 3, lines 1-6;

page 3, line 26 – page 4, line 7;

page 5, line 10-17;

page 6, line 9-23;

page 16, line13 - page17, line 4;

page 19, line 23 – page 20, line 20;

Claim 15 also recites that an alarm is activated when predefined trends in the data are detected (page 20, lines 25-27).

(vi) Grounds of Rejection to be Reviewed on Appeal

Claims 1-5, 7-9 and 11 stand rejected as anticipated by U.S. Patent No. 5,153,828 (Inoue et al.).

Claims 12, 14 and 15 stand rejected as obvious over U.S. Patent No. 5,153,828 (Inoue et al.).

Claim 6 stands rejected as obvious over U.S. Patent No. 5,153,828 (Inoue et al.) in view of U.S. Patent No. 5,876,387 (Killian et al.).

Claim 10 stands rejected as obvious over U.S. Patent No. 5,153,828 (Inoue et al.) in view of U.S. Patent No. 5,989,234 (Valerio et al.).

(vii) Argument

Claim Rejections – 35 USC §102

The rejection of claims 1-5, 7-9 and 11 as anticipated by U.S. Patent No. 5,153,828 (Inoue et al.) is traversed. Inoue does not disclose the structure recited in the current claims. In particular, Inoue fails to disclose:

"a controller connected to the sensor and configured to receive current procedure data from the sensor, save the data to create historical procedure data, compare the current procedure data to the historical procedure data and activate an alarm when predefined trends in the data are detected"

In the last action it was suggested that the [collected] data taught by Inoue is procedure data. Even if the weight of collected blood data collected by the Inoue system were properly considered to be "procedure" data, Inoue does not disclose a controller configured to ***compare*** that data to historical procedure data and activate an alarm when predefined trends are detected. It appears that Inoue does not keep or look back at previously collected procedure data points at all. Rather, it takes the currently detected blood bag weight, uses that data point in an algorithm with other non-varying, non-procedure information in order to generate the current value for a "yet-to-be-collected amount" of blood. Even if the Inoue system takes several blood bag weight measurements during the course of a blood collection procedure, it does not appear to store or compare those multiple data points. It only uses the currently measured data point at any given time. Inoue does not disclose a collection system with a controller configured to compare current and historical procedure data.

In contrast, applicants' invention relies on comparing current blood volume information with one or more past blood volume measurements from the same ongoing procedure so that trends in the current procedure can be identified that will inform a healthcare provider on the progress of a patient's healing.

Furthermore in the last action it was asserted that applicants are incorrect to argue that Inoue does not teach comparing historical data to current data because

Inoue teaches that a memory 66 stores previously collected data. The examiner's assertion is incorrect, first because applicants' claims recite that the controller...compares the current *procedure* data to the historical *procedure* data, not just any data pulled from memory. Inoue may teach that its CPU has a memory 66, but it is used to hold only predetermined set- points, not historical procedure data collected during the procedure. At column 7 lines 6-19, Inoue sets forth the type of set-point information retained in the memory 66. Later, at column 7, lines 58-64 Inoue illustrates how the system uses the saved set-points: the CPU compares currently detected data only to the set-points contained in memory. The Inoue system does not store historical procedure data at all, let alone compare historical *procedure* data to current *procedure* data.

Inoue uses CPU memory to hold set-point information, and then current information from sensors is compared to that set-point information in order to control the machine's performance, keeping it near set-point operating levels. The type of system described in Inoue is clearly different from the system of applicants' claims. Applicants' claims define a system that permits monitoring of procedure trends indicative of a patient's condition by comparing data points collected over time during a single procedure.

Furthermore there can be no misunderstanding about what is meant by "current procedure data" and "historical procedure data" as used in applicants' claims because the terms are defined in the claims themselves. In applicants' claim 1 it is stated that a controller is connected to a sensor to receive "current procedure data" from the sensor. Then, the current procedure data is saved to create "historical procedure data". "Historical procedure data" is not just set-points; rather it is "current procedure data" that was earlier recorded during the same procedure. Comparing the current procedure data to the historical procedure data can reveal trends happening in the procedure that are helpful in identifying problems in the healing of the patient. The Inoue system in no way attempts to provide such a means for patient monitoring and its disclosure certainly does not disclose or suggest the system defined in applicants' claims.

Accordingly, because the '828 patent does not disclose a system configured to

compare historical procedure data with current procedure data collected from a fluid collection suction pathway, it should not be considered to anticipate the claims of the present application.

Claim Rejections – 35 USC § 103

Applicants traverse the rejection of claims 6, 10, 12, 14 and 15 as obvious and request reconsideration. First, each obviousness rejection relies, at least in part, on the disclosure of Inoue and as explained above that patent fails to disclose or suggest significant elements of the applicants' claims, namely a system that compares current procedure data to historical procedure data. Because Inoue fails to disclose or suggest that element of the claims, it should not be considered to render obvious applicants claims containing that limitation.

In addition, regarding claim 12, the assertion in the last action that the "interval at which data is sampled affects the accuracy if the information displayed to the user" dose not appear to hold true for in the Inoue system. Applicants maintain that because the data collected (weight of blood bag) is merely plugged into a formula with other fixed values in order to generate the "yet-to-be-collected amount" of blood, it seems that changing the frequency of data collection would not impact the accuracy of each individual "yet to be collected" value. It would merely change how often a "yet to be collected" value could be displayed. Because Inoue does not compare data points collected at different times during a procedure but only presents a currently measured data point – increasing the frequency of such display would not enhance accuracy. Applicants maintain that one skilled in the art, with the Inoue system before them, would not be motivated to alter the display to show readings in 15 minute intervals to increase accuracy of the data being shown by the system.

Accordingly for the reasons set forth above, all rejections of applicants' claims should be withdrawn.

(viii) Claims Appendix

1. (Previously presented) A postoperative fluid monitoring and alert system comprising:

a fluid collection device having a vacuum reservoir configured to be placed in communication with a suction pathway that is at least partially defined by a surgical drain tube;

at least one liquid collection sensor configured to obtain data from the suction pathway;

a controller connected to the sensor and configured to receive current procedure data from the sensor, save the data to create historical procedure data, compare the current procedure data to the historical procedure data and activate an alarm when predefined trends in the data are detected.

2. (Original) A postoperative fluid management system as defined in Claim 1 wherein:

the controller monitors communication between the vacuum reservoir and suction pathway and is configured to activate an alarm when communication is opened between the reservoir and pathway excessively.

3. (Original) A postoperative fluid management system as defined in Claim 2 wherein: the vacuum reservoir is selectively opened to the suction pathway by a valve connected to the controller and the frequency of valve opening is monitored by the controller.

4. (Original) A postoperative fluid management system as defined in Claim 3 wherein the controller activates opening of the valve based on pressure data received from a pressure sensor in fluid communication with the suction pathway.

5. (Original) A postoperative fluid management system as defined in Claim 4 wherein: the vacuum reservoir is a closed tank connected to a compressor

configured to be selectively operated to generate vacuum in the tank.

6. (Original) A postoperative fluid management system as defined in Claim 4 wherein the vacuum reservoir is joined to a facility-wide source of suction.

7. (Original) A postoperative fluid management system as defined in Claim 1 further comprising a visual display connected to the controller and being configured to display information regarding liquid collection volume over predetermined time intervals during a fluid drainage procedure.

8. (Original) A postoperative fluid management system as defined in Claim 1 wherein the alarm is an audible alarm.

9. (Original) A postoperative fluid management system as defined in Claim 7 wherein the alarm comprises a visual indication on the visual display.

10. (Original) A postoperative fluid management system as defined in Claim 1 wherein the fluid collection device comprises an autotransfusion device.

11. (Original) A postoperative fluid management system as defined in Claim 10 wherein the autotransfusion device is a peri-operative system and the controller is provided with intra-operative and postoperative modes of operation.

12. (Previously presented) A postoperative fluid management system as defined in Claim 7 wherein historical procedure data and current procedure data is displayed on the visual display graphically indicating the volume of liquid collected in fifteen minute time intervals.

13. (Withdrawn) A method of monitoring postoperative fluid drainage procedure comprising:

providing fluid collection device having a vacuum reservoir in selective fluid communication with a suction pathway, a liquid collection sensor configured to obtain data from the suction pathway and a controller connected to the sensor;
joining a surgical drain tube to the suction pathway;
opening the vacuum reservoir to the suction pathway aspirate fluid from a patient's surgical site through the pathway;
monitoring the amount of liquid collected with the sensor;
transmitting current data from the sensor to the controller and storing the data during the course of the surgical site drainage procedure to create historical data;
observing alerts generated by the controller regarding trends identified between the historical and current data.

14. (Previously presented) A postoperative fluid management system as defined in Claim 12 wherein historical procedural data from a plurality of previous time intervals are displayed on the visual display along with the current procedure data.

15. (Previously presented) A postoperative fluid monitoring and alert system comprising:
a fluid collection device having a vacuum reservoir configured to be placed in communication with a suction pathway that is at least partially defined by a surgical drain tube;
at least one liquid collection sensor configured to obtain data from the suction pathway;
a controller connected to the sensor and having instructions to receive current procedure data from the sensor, save the data to create historical procedure data, compare the current procedure data to the historical procedure data and activate an alarm when predefined trends in the data are detected.

(ix) Evidence Appendix

No evidence is submitted pursuant to 37 CFR sections 1.130, 1.131 or 1.132.

(x) Related Proceedings Appendix

There are no related proceedings.

Respectfully submitted,

Date: March 13, 2009

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,060	03/10/2004	Alec Bobroff	HM-04-PT-03-NP	5665

41883 7590 02/13/2009

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 02/13/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No. 10/798,060	Applicant(s) BOBROFF ET AL.	
	Examiner MELANIE HAND	Art Unit 3761	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *12 January 2009* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☒ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☒ Other (including any explanation in support of the above items):

Section V: Summary of claimed subject matter must identify and map all independent claims on appeal (claim 15) to specification by page and line number or paragraph number. The entire brief is not required for this correction.

/CP/
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